Atty. Dkt. No. 071949-2705

REMARKS

Claims 1-10 and 17 are pending in this application. Claims 11-16 have been cancelled. Claim 1 has been amended to further define the invention. The amendments find support in the application and originally filed claims. Support for the claim 1 amendment can be found, for example, at p. 30, lines 21-28. Accordingly, the present amendments and new claims raise no issue of new matter.

Obviousness-Type Double Patenting

The rejection of claims 1, 8, 9 and 17 for allegedly being unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 1, 11-19 of U.S. Patent No. 5,947,124 ("the '124 patent") is respectfully traversed.

Claims 1, 8, 9 and 17 are directed to a method of determining the ratio of oxidized to reduced cardiac troponin I using a signal from a complex containing 1) a first antibody that binds both oxidized and reduced cardiac troponin I in an amount proportional to their ratio in the sample and 2) a second antibody that binds to one of oxidized cardiac troponin I bound to the first antibody or reduced cardiac troponin I bound to the first antibody.

The specified claims of the '124 patent and the patent itself fails to disclose s several critical claim elements. For example, the cited claims of the '124 patent do not describe any single assay where one determines the ratio of oxidized to reduced cardiac troponin I. The '124 patent claims and discloses methods of determining a ratio of oxidized to reduced cardiac troponin I by measuring permutations combining **two** of the following three concentrations: 1) concentration of oxidized form 2) concentration of reduced form and 3) concentration of total (oxidized and reduced) form. Thus, the concentration of oxidized and that of reduced tropinin I is measured in separate assays.

The cited claims of the '124 patent are also deficient in teaching or suggesting that the assay includes a first antibody that binds oxidized and reduced cardiac troponin I **in an amount**

proportional to their ratio in the sample. The '124 patent claims further fails to disclose that a complex containing **two** different antibodies is formed in the assay. The cited patent only refers to using different antibodies but does not specify to use the antibodies together.

Furthermore, the assertion that the specified '124 patent claims describe "a standard curve for analysis" as required by pending claim 8 is incorrect. The standard curve of the '124 patent is used to correlate a **measured ratio** of oxidized to reduced troponin I to determine the time of myocardial infarction. Col. 10, lines 5-12. The standard curve of claim 8 is used to correlate a **measured assay signal** to determine the ratio of oxidized to reduced troponin I. Thus, the reference to a standard curve in the '124 patent does not teach or suggest its use as recited in claim 8.

Applicant also wishes to mention that claim 9 is distinct from the recited '124 patent claims for the additional reason that it uses a normalizing factor to correlate a measured signal from claim 1 to a ratio of oxidized to reduced cardiac troponin I as required by claim 9. The Examiner has failed to allege that such normalizing factor is disclosed in the '124 patent.

For at least these reasons claims 1, 8, 9 and 17 constitute patentably distinct species of methods for determining the ratio of oxidized to reduced troponin I over the patented claims. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. § 112

The Examiner's assertion that the step (a)(ii) as used in claim 1 is allegedly indefinite is respectfully traversed. Applicant respectfully submits that one of ordinary skill in the art would understand the step as used in the claims in light of the specification. However, in order to reduce the issues and expedite prosecution, claim 1 has been amended to further clarify Applicant's invention. It is noted that the amended language was previously discussed with the Examiner and resulted in an earlier informal communication. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. § 102(e) under Buechler

The rejection of claims 1-10 and 17 as allegedly being anticipated by Buechler (U.S. Patent No. 5,947,124) ("the '124 patent") is respectfully traversed. As discussed in detail above, the '124 patent fails to disclose several claim limitations including 1) a single assay that determines the ratio of oxidized to reduced cardiac troponin I; 2) use of a first antibody that binds both oxidized and reduced forms of cardiac troponin I "in an amount proportional to their ratio in the sample," and 3) forming a complex containing a first and second antibody. As such, the '124 patent does not anticipate any of the pending claims. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Applicant notes that the Examiner mentions that the instant application has no recorded assignment and thus has been treated as a "no-common assignee for art rejection purposes" citing to Chapter 800, Chart II-B. Office Action, page 4. Applicant points out that Chart II-B is for "Different Inventions" and, therefore, is not relevant to the instant 102(e) rejection for anticipation. Chart II-A is relevant to a rejection of anticipation, however, common ownership does not impact a rejection under 102(e). In any event, Applicant notes that Biosite, Incorporated, is the Assignee of the present application by virtue of an assignment from the parent application, U.S. serial No. 09/081,722, which covers continuation applications and a change of name. These documents, which have been filed for recordation, are attached herewith for the Examiner's convenience.

CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to contact the undersigned so that a prompt disposition of this application can be achieved.

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date August 2, 2006

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